

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KYOWA HAKKO BIO, CO., LTD.,
BIOKYOWA, INC., KYOWA HAKKO
BIO U.S. HOLDINGS, INC., and KYOWA
HAKKO U.S.A., INC.,

Plaintiffs,

v.

AJINOMOTO CO., INC., AJINOMOTO
HEALTH & NUTRITION NORTH
AMERICA, INC., and AJINOMOTO
FOODS NORTH AMERICA, INC.,

Defendants.

C.A. No. 17-00313-MSG

Jury Trial Demanded

AJINOMOTO'S OBJECTIONS TO CLAIM CONSTRUCTION OPINION

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TABLE OF CONTENTS

| | |
|---|-----|
| Table of Contents..... | i |
| Table of Authorities | ii |
| List of Exhibits..... | iii |
| Introduction..... | 1 |
| Argument | 1 |
| A. Ajinomoto’s construction of “adding crystals … to the medium” is the ordinary meaning of the term, as evidenced by every example in the ’723 patent, dictionary definitions, and the scientific literature. | 2 |
| B. Disavowal is irrelevant to the analysis of what the term “adding crystals of the amino acid … to the medium” means. | 4 |
| C. There is no mechanism by which to apply Kyowa’s construction to a commercial process. | 5 |
| Conclusion | 7 |

TABLE OF AUTHORITIES

Cases

| | |
|--|---|
| <i>Phillips v. AWH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005),..... | 1 |
|--|---|

| | |
|---|---|
| <i>Teva Pharmaceuticals USA Inc. v. Sandoz Inc.</i> , 135 S. Ct. 831 (2015)..... | 1 |
|---|---|

Rules

| | |
|-------------------------|---|
| Fed. R. Civ. P. 72..... | 1 |
|-------------------------|---|

LIST OF EXHIBITS

The exhibits relied upon in these objections were previously filed as noted below and will be submitted with the courtesy copies of these objections delivered to chambers:

From D.I. 80, Rao Declaration:

Ex. 1 RE 45,723 (“the ’723 patent”)

Ex. 21 *Webster’s II: New College Dictionary* (3d 2005), AJ108950–52, definition of *to*.

From D.I. 83, Colvin Declaration:

Ex. F-4 *The New Oxford American Dictionary* (2001), definition of *add*.

From D.I. 102, Mandrusiak Declaration:

Ex. 29 Transcript of Deposition of Dr. Michael Doherty, May 17, 2019.

From D.I. 105, Colvin Declaration:

Ex. 5A Wong *et al.*, *Contact Secondary Nucleation as a Means of Creating Seeds for Continuous Tubular Crystallizers*, Cryst. Growth Des. 2013, 13, 2514–2521.

Ex. 6A Nagy *et al.*, *Comparative Performance of Concentration and Temperature Controlled Batch Crystallizations*, Journal of Process Control 18 (2008) 399–407.

Pursuant to Fed. R. Civ. P. 72(b) and 28 U.S.C. § 636(b)(1), Ajinomoto submits these objections to the construction of the claim phrase “adding crystals of the amino acid … to the medium” in the October 9, 2019 claim construction opinion (“Op.,” D.I. 113 at 23).

Introduction

The opinion focuses, as it should, on the ’723 patent’s outcome-determinative term, “average particle size.” In construing the “adding crystals … to the medium” term, however, the opinion does not consider and weigh appropriately the evidence demonstrating that the ordinary meaning of adding crystals to the medium entails putting crystals into the medium, as repeatedly described in the specification and in the sole scientific publication that distinguishes what it means to add crystals to a medium from what it means to generate crystals within a medium. The issue for the Court’s *de novo* consideration is: Does the ordinary and customary meaning of “adding crystals … to the medium” in the context of the intrinsic record, as viewed by one of ordinary skill in the art, entail “putting crystals into the medium”? *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005).

Argument

A magistrate judge’s claim constructions are reviewed *de novo*, while underlying factual determinations involving extrinsic evidence are reviewed for clear error. *See* Fed. R. Civ. P. 72; *Teva Pharmaceuticals USA Inc. v. Sandoz Inc.*, 135 S. Ct. 831, 841–842 (2015). Ajinomoto does not dispute the factual findings in the claim construction opinion that there are at least three ways to introduce crystals in a medium and that pouring and dumping are not the only ways to introduce crystals. Nor does Ajinomoto dispute the opinion’s description of the subject technology with respect to seeding a fermentation broth with crystals. (Op. at 3.) But, the ultimate claim-construction determination—that, in the context of the patent, “adding crystals … to the medium” is the same as “introducing crystals to the medium that were not there before”

(Op. 22) and includes “agitating[] or shocking the broth” (Op. 24)—is incorrect because it contradicts the plain meaning of what it means to add something to something else, the specification’s description of adding crystals to the medium, and the scientific literature.

| Ajinomoto’s Proposed Construction | Kyowa’s Proposed Construction | Claim Construction Opinion |
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| putting crystals of the amino acid ... into the medium This term does not encompass crystals that form in the medium. | Introducing crystals to the medium that were not there before, which are the same crystals that the claim later requires “grow ... and accumulate in the medium” | Introducing crystals to the medium that were not there before, which are the same crystals that the claim later requires “grow ... and accumulate in the medium” |

A. Ajinomoto’s construction of “adding crystals ... to the medium” is the ordinary meaning of the term, as evidenced by every example in the ’723 patent, dictionary definitions, and the scientific literature.

Aside from the conclusory opinion of Kyowa’s expert, Dr. Michael Doherty, all evidence of record, including the intrinsic evidence, is either irrelevant or supports Ajinomoto’s proposed construction that “adding crystals of the amino acid ... to the medium” means “putting crystals of the amino acid ... into the medium.” None of the literature cited by Dr. Doherty or submitted by Kyowa ever discusses “adding” or “added” crystals, except to describe external crystals that are put into a medium. There is no objective evidence that one of ordinary skill in the art would have understood the term “adding crystals of the amino acid ... to the medium” to include shock-seeding, breaking crystals through secondary nucleation, or other forms of generating new crystals out of the amino acid that is already in the medium. (See Op. at 23.)

In the claim construction opinion, the first of the two paragraphs analyzing the disputed term begins by adopting Kyowa’s misstatement that Ajinomoto’s construction is limited to pouring or dumping pre-sized crystals into the broth. (*Compare* D.I. 113, Op. at 23 *with* D.I. 88, Kyowa Br. at 25.) Kyowa’s characterization is incorrect because Ajinomoto’s construction is broad enough

on its face to encompass any method of putting crystals into the broth. For example, if one wishes to add a slurry of crystals to a crystallizer, “the slurry can be directed into a downstream crystallizer” by flowing the slurry through conduit. (D.I. 105, Ex. 5A at 1515, col. 2.)

Each and every description (15 total) of the “to be added” crystals in the ’723 patent’s specification involves putting pre-existing crystals into the broth/medium. Consistent with the patent’s specification, the dictionary definitions submitted by both parties support Ajinomoto’s construction that adding crystals *to* a medium means putting crystals into the medium:

- add: “put (something) in or on something else so as to improve or alter its quality or nature: *chlorine is added to the water to kill bacteria*”
(D.I. 83, Ex. F-4, *The New Oxford American Dictionary* at 18, “add”.)
- to: “in a direction toward <went *to* town>”
(D.I. 80, Ex. 21, *Webster’s II* at AJ108952, “to”.)

The definitions of “add” and “to” demonstrate that, when crystals are *added to* a medium, they are put into the medium, not generated within the medium. The claim construction opinion does not consider these dictionary definitions and does not acknowledge that every example in the ’723 patent of adding crystals to the medium involves putting pre-existing crystals into the broth/medium.

Outside of Kyowa’s expert’s conclusions—which contradict the ’723 patent’s instructions and examples for adding crystals to the medium—no evidence supports Kyowa’s proposal that “*adding crystals of the amino acid … to the medium*” somehow encompasses the generation of new crystals from the amino acid that is already *within* the medium. *See Vitronics Corp. v. Conceptronic*, 90 F.3d 1576, 1584 (Fed. Cir. 1996) (“Only if there were still some genuine ambiguity in the claims, after consideration of all available intrinsic evidence, should the trial court have resorted to extrinsic evidence, such as expert testimony”.) The other extrinsic evidence, including the scientific articles that Kyowa submitted with its claim-construction

briefs, never equates shock-seeding or crystal breakage to “adding crystals … to [a] medium.”

On the other hand, the only article that uses the term “add” in the context of seed crystals explicitly distinguishes crystals “added” to a medium from crystals “generated” within a medium:

Seeds can be added *or* generated at the beginning of the batch. … For “unseeded operation” where the seeds are generated *in* the batch, the operating line first reaches the metastable limit to generate seeds

(DI 105, Ex. 6A, Nagy et al. at 400, col. 2, emphases added.)

This article, submitted by Kyowa at the close of claim-construction briefing, was not considered in the claim construction opinion. Nonetheless, as pointed out at the claim-construction hearing, the article demonstrates that one of ordinary skill in the art understands that adding crystals to the medium is different from generating crystals in the medium. (Hr’g Tr. at 86:10–24.)

Thus, the only pre-litigation documentation of what it means to *add* something *to* something else—the ’723 patent, the dictionary definitions, and Exhibit 6A—support Ajinomoto’s construction, warranting review and correction of the claim construction opinion.

B. Disavowal is irrelevant to the analysis of what the term “adding crystals of the amino acid … to the medium” means.

The second paragraph of analysis in the claim construction opinion adopts Kyowa’s innocuous observation that the disputed term’s meaning is not limited through disavowal. (Op. at 23.) Ajinomoto agrees. The fact that each of the patent’s many examples of adding crystals of the amino acid to the medium describe putting external crystals into the medium merely supports Ajinomoto’s construction. Commensurate with the ordinary meaning of “adding crystals … to the medium,” the ’723 patent consistently and repeatedly describes that the crystals added to the medium are external, pre-made crystals that are put into the medium, just like ingredients are added in a recipe. Nothing in the intrinsic record broadens the ordinary meaning of the term

“adding … to” to mean “introducing” or “forming in.”

C. There is no mechanism by which to apply Kyowa’s construction to a commercial process.

Kyowa’s construction, adopted in the claim construction opinion, cannot be practically applied to a real-life process to determine whether the crystals introduced in the medium (by any method) meet the average-particle-size range specified in the claims. As acknowledged by Kyowa and its expert, the agitator blades that stir the crystals in the broth continually cause crystal nuclei to break off of the crystals in the broth. (D.I. 102, Ex. 29, Doherty Tr. at 118:13–22, 120:24–121:4.) That process is called secondary nucleation. (D.I. 84, Doherty Decl. ¶ 24; D.I. 88, Kyowa Br. at 26.) And, while secondary nucleation is creating new crystals inside in the medium, all crystals, old and new, are growing. (D.I. 102, Ex. 29 at 116:17–21.) Consequently, there is no means by which to ascertain the size of the crystals when they were first “introduced,” whether as an external crystal added to the broth or as a crystal formed internally within the broth.

Even Kyowa’s expert, Dr. Doherty could not figure out how to determine the average particle size of the crystals when some originate as external crystals that are put in the broth and others originate as new crystals that are generated within the broth by secondary nucleation. When confronted with the problem of trying to include secondary nuclei in the calculation of average particle size, Dr. Doherty first said that crystals formed through secondary nucleation should be included in the calculation “If that’s your primary means of creating seeds.” (D.I. 102, Ex. 29 at 125:23–126:12.) But, he was unable to explain (“I don’t have an opinion on that”) what crystals should be considered in the average-particle-size calculation when secondary nucleation is not the primary means of creating seeds. (*Id.*) Similarly, even if secondary nucleation was the primary method of creating seeds, Dr. Doherty had no explanation (“I actually haven’t formed an

opinion on that”) for how average particle size would be calculated when both externally-created crystals and nucleated crystals were present in the medium. (Ex. 29 at 126:13–127:7.)

Unsurprisingly, the ’723 patent does not factor the size of crystals created by secondary nucleation into the average-particle-size calculation of the crystals added to the medium. This is because the patent does not consider secondary nucleation to constitute “adding crystals … to the medium.” Thus, the problem that stumped Kyowa’s expert is avoided.

Ajinomoto’s construction also avoids this problem by staying true to the ’723 patent and the common-sense, ordinary meaning of what it means to add something to something else. When crystals are put in a medium, the average particle size can be determined prior to adding the crystals to the broth, as described in the ’723 patent. (*See, e.g.*, D.I. 80, Ex. 1, ’723 patent, col. 8:22–32, 9:44–50, 9:64–67.) Ajinomoto’s construction is also easily reconcilable with the claim construction opinion’s construction of “before” because the added crystals must be put in the medium before more than a slight amount of the amino acid deposits in the broth. (*Id.*, col. 6:43–49, claims 1 and 2.) Assuming *arguendo* that the “average particle size” term is not indefinite, the to-be-added crystals can be measured prior to putting them in the broth to determine whether they fall within the claimed average-particle-size range, and the broth can be observed to determine whether adding occurs “before crystals of the amino acid deposit” in the broth. (*Id.*, claims 1 and 2.)

Thus, Ajinomoto’s construction overcomes the pitfalls of Kyowa’s construction, which is unworkable when pre-made crystals are put in the broth and new crystals are generated within the broth. Therefore, the Court should adopt Ajinomoto’s claim construction to address this point.

Conclusion

The construction of “adding crystals … to the medium” erroneously adopts Kyowa’s proposed construction and logic, which contradicts the intrinsic evidence and finds support only in the post-litigation statements of Kyowa’s expert witness. Ajinomoto’s construction aligns with the patent’s description of adding crystals to a fermentation broth and is consistent with the pre-litigation extrinsic evidence. Therefore, this Court should correct the claim construction opinion to construe “adding crystals of the amino acid … to the medium” to mean “putting crystals of the amino acid into the medium.”

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